Pharmacy Medical Necessity Guidelines: Elidel® (pimecrolimus) & Protopic® (tacrolimus)

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Elidel (pimecrolimus) and Protopic (tacrolimus) are indicated as second-line therapies for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
See Attachment		
Step-2		
pimecrolimus	Requires prior use of two (2) Step-1 drugs	Requires prior use of two (2) Step-1 drugs
tacrolimus		
Step-3		
Elidel	Requires prior use of a drug on Step-2 or Step-3	Not Covered
Protopic		

Automated Step Therapy Coverage Criteria

The following stepped approach applies to Elidel (pimecrolimus) and Protopic (tacrolimus) coverage by the plan:

Step 1: Medications on Step-1 are covered without prior authorization (*See Attachment 1*)
Step 2: The plan may cover medications on Step-2 if the following criteria are met:
- The member has had a trial of at least two (2) Step-1 medications of medium or greater potency within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Step-3: The plan may cover medications on Step-3 if the following criteria are met:

- The member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a non-covered medication within the previous 180 days listed below under the limitations section as evidenced by physician documented use, excluding the use of samples.

Coverage Criteria for Members Not Meeting the Automated Step Therapy Coverage Criteria at the Point of service
The following stepped approach applies to Step-2 and Step-3 medications covered by the plan:

Step 2: The plan may cover Step-2 medications if the following criteria are met:
- The Member has had a trial of at least two (2) Step-1 topical steroid medications of medium or greater potency or one Step-2 medication within the previous 180 days as evidenced by physician documented use, excluding the use of samples

OR

- The Member has a physician documented contraindication or intolerance to a Step-1 medication

Step-3: The plan may cover Step-3 medications if the following criteria are met:
- The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by physician documented use, excluding the use of samples

OR

- The Member has a physician documented contraindication or intolerance to a Step-2 medication

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received a **non-covered** medication, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

Note: The plan may authorize coverage of Elidel (pimecrolimus) or Protopic (tacrolimus) for facial or intertriginous psoriasis for members when the following criteria are met:

1. The Member has the diagnosis of mild to moderate atopic dermatitis (eczema) or facial or intertriginous psoriasis

AND

2. Documentation of one of the following:
   a. The Member is not a candidate for medium to high potency corticosteroid therapy (e.g., eyelid dermatitis, facial dermatitis, or dermatitis associated with genital area eruptions)

   OR

   b. The Member has a contraindication to topical corticosteroids

Attachment 1

Potency	Products	Drug Dosage Form	Strength
Very High	Betamethasone dipropionate augmented	gel, lotion, ointment	0.05%
	halobetasol	cream	0.05%
High	Betamethasone dipropionate augmented	cream	0.05%
	betamethasone dipropionate	cream	0.05%
	betamethasone valerate	ointment	0.1%
	fluocinonide	cream, cream (emulsified)	0.05%
	fluticasone	ointment	0.005%
	mometasone	ointment	0.1%
	triamcinolone	cream, ointment	0.5%
Medium	betamethasone dipropionate	lotion	0.05%
	betamethasone valerate	cream	0.1%
	Fluocinolone	cream, ointment	0.025%

Potency	Products	Drug Dosage Form	Strength
	Fluticasone	cream	0.05%
	mometasone	cream, solution (lotion)	0.1%
	prednicarbate	ointment	0.1%
	triamcinolone	cream, lotion, ointment	0.025%, 0.1%

LIMITATIONS

- Medications on Step-2 and Step -3 are not covered unless the above step therapy criteria are met.
- Non-covered medications for Small Group and Exchange formularies include the following brand-name products: Elidel and Protopic. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.

CODES

None

REFERENCES

1. AHFS Drug Information. Available with subscription at: ashp.org. Accessed August 29, 2009.
2. Elidel (pimecrolimus) [package insert]. Merignac, France. MEDA Manufacturing. December 2017.
3. Protopic (tacrolimus) [package insert]. Madison, NJ. LEO Pharma Inc. July 2017.
4. Lebwohl, M. et al. Tacrolimus ointment is effective for facial and intertriginous psoriasis. Journal of the American Academy of Dermatology 51.5 (2004):723-30.
5. UpToDate [database on the Internet]. Wolters Kluwer. Updated periodically. uptodate.com [available with subscription]. Accessed 2016 September 9.
6. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. micromedexsolutions.com [available with subscription]. Accessed June, 2014.

APPROVAL HISTORY

September 11, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- November 9, 2010: Removed the listing for fluocinolone cream 0.2%, no longer available. Removed "lotion" from mometasone 0.1%, not available
- May 10, 2011: Added facial or intertriginous psoriasis to the criteria for approval
- September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
- March 13, 2012: No changes
- June 12, 2012: Administrative Update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs
- March 12, 2013: No changes
- February 11, 2014: No changes
- January 13, 2015: Added tacrolimus to Step-2 and moved Protopic to Step-3 of the medical necessity guidelines.
- October 6, 2015: Effective 1/1/16, brand Protopic will no longer be covered on the Exchange formularies.
- January 1, 2016: Administrative change to rebranded template.
- October 18, 2016: No changes
- February 14, 2016: No changes. Administrative update to medications listed in Attachment 1.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- February 13, 2018: Administrative update, added prednicarbate 0.1% ointment to attachment 1.
- March 12, 2019: Effective July 1, 2019, move Elidel to Step-3 of the medical necessity guidelines and non-covered for Large Group formularies and non-covered for Small Group and Exchange formularies (effective December 26, 2018, due to the launch of the generic, pimecrolimus, which is added to Step-2. Updates Step Therapy criteria and limitations section to be in line with step

therapy logic. Added facial dermatitis as an example of why the Member is not a candidate for medium to high potency corticosteroid therapy.

- November 10, 2020: Updated attachment 1 to include all preferred topical corticosteroids. No changes to coverage criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.